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DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE

D1228B

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

February 28, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Wil Lepeska
President
The Synaptic Corporation
3177 South Parker Road
Aurora, Colorado 80014

PURGED

Ref. # - DEN-97-11

Dear Mr. Lepeska:

During an inspection of your firm located in Aurora, Colorado, on August 29 through October 17, 1996, Investigator Jon S. Curran from the Denver District Office of the Food and Drug Administration, determined that your firm manufactures the
The is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish written manufacturing specifications and processing procedures in order to assure that the device conforms to its original design or any approved changes in that design. For example, there is no documentation demonstrating the validation of ECN's developed to address the replacement of the power jack.

2. Failure to establish a Device Master Record which includes all device specifications including appropriate drawings, composition, formulation and component specifications. For example, the Master Record for the does not include the checksum value of the software, which is used to assure that are correctly programmed.

3. Failure of the quality assurance program to have adequate procedures in place to assure approval or rejection of finished devices. For example, the Procedure, dated 7/8/94 specifies a tolerance of % for the frequency test, however acceptable values range up to %.

The is misbranded within the meaning of Section 502 (o) in that a notice respecting the device was not provided to the FDA as required by Section 510 (k) and 21 CFR 807.81 (a) (3) (ii) for new intended uses, including Alzheimer's disease, remineralization, insomnia, depression, anxiety, reflex sympathetic dystrophy, extremity venous malformations, tissue healing, appetite reduction, sleep improvement, reduction of erratic behavior, dental pain, TMJ pain, electrolysis pain, post knee-surgery pain, heel and pedal pain, fracture pain, rotator cuff strains, sciatica and menstrual pain.

The is also adulterated within the meaning of Section 501 (f) (1) (B) in that it is a Class III device under Section 513 (f) and does not have an approved application for premarket approval in effect pursuant to Section 515 (a) or approved application for an investigational device exemption under Section 520 (g).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Your reply should be sent to the Food and Drug Administration, Denver District Office, Attention: Regina A. Barrell, Compliance Officer, at the above address.

Sincerely,

Gary C. Dean
District Director

cc: Mr. Donald J. Zahorik
Executive Vice President and Chief Operating Officer
The Synaptic Corporation
3177 South Parker Road
Aurora, Colorado 80014

Enclosure:
FDA 483